Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

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Elvitegravir (EVG) (Last updated April 14, 2020; last reviewed April 14, 2020)

Formulations

Tablet: Discontinued by the manufacturer. Elvitegravir is only available in fixed-dose combination (FDC) tablets.

Fixed-Dose Combination Tablets:

- [Genvoya] Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg
- [Stribild] Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg

When using FDC tablets, refer to other sections of the Drug Appendix for information about the individual components of the FDC. See also Appendix A, Table 2. Antiretroviral Fixed-Dose Combination Tablets: Minimum Body Weights and Considerations for Use in Children and Adolescents.

For additional information, see Drugs@FDA or DailyMed.

Dosing Recommendations

[Genvoya] Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (TAF)

Child (Weighing <25 kg) Dose:

- There are no data on the appropriate dose of Genvoya for children weighing <25 kg.

Child and Adolescent (Weighing ≥25 kg) and Adult Dose:

- One tablet once daily with food in antiretroviral therapy (ART)-naive patients. This dose of Genvoya can also be used to replace the current antiretroviral (ARV) regimen in patients who have been virologically suppressed (HIV RNA <50 copies/mL) on a stable ART regimen for at least 6 months with no history of treatment failure and no known mutations associated with resistance to the individual components of Genvoya.

[Stribild] Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate (TDF)

Child and Adolescent (Weighing <35 kg) Dose:

- There are no data on the appropriate dose of Stribild for children or adolescents weighing <35 kg.

Adolescent (Weighing ≥35 kg and Sexual Maturity Rating [SMR] 4 or 5) and Adult Dose:

- One tablet once daily with food in ART-naive patients. This dose of Stribild can also be used to replace the current ARV regimen in patients who have been virologically suppressed (HIV RNA <50 copies/mL) on a

Selected Adverse Events

Elvitegravir-Associated Adverse Events:

- Diarrhea

Stribild-Associated Adverse Events:

- Nausea
- Diarrhea
- Fatigue
- Headache

TDF-Specific Adverse Events:

- Glomerular and proximal renal tubular dysfunction
- Decreased bone mineral density
- Flatulence

Cobicistat-Specific Adverse Events:

- Benign increases in serum creatinine levels (reductions in estimated glomerular filtration) due to inhibition of tubular secretion of creatinine

Genvoya-Associated Adverse Events:

- Nausea
- Diarrhea
- Fatigue
- Headache

TAF-Specific Adverse Events:

- Increased levels of low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, and total cholesterol

Cobicistat-Specific Adverse Events:

- Benign increases in serum creatinine levels

stable ART regimen for at least 6 months with no history of treatment failure and no known mutations associated with resistance to the individual components of Stribild.

(reductions in estimated glomerular filtration) due to inhibition of tubular secretion of creatinine

Special Instructions

- Administer both Genvoya and Stribild with food.
- EVG should be administered at least 4 hours before or after antacids and supplements or multivitamins that contain iron, calcium, aluminum, and/or magnesium.
- When using Stribild, which contains TDF, monitor estimated creatinine clearance (CrCl), urine glucose, and urine protein at baseline and every 3 to 6 months while on therapy. In patients who are at risk of renal impairment, also monitor serum phosphate. Patients with an increase in serum creatinine levels >0.4 mg/dL should be closely monitored for renal safety.
- Screen patients for hepatitis B virus (HBV) infection before using emtricitabine (FTC), TDF, or TAF. Severe acute exacerbation of HBV can occur when FTC, TDF, or TAF are discontinued; therefore, monitor hepatic function for several months after stopping therapy with FTC, TDF, or TAF.
- For information on crushing and cutting tablets, please see this table from Toronto General Hospital.

Metabolism/Elimination

- EVG is metabolized by cytochrome P450 (CYP) 3A4 and is a modest inducer of CYP2C9.
- EVG should only be used with the pharmacokinetic enhancer (boosting agent) cobicistat in Stribild or Genvoya. Refer to the TDF and TAF sections for further details.

Elvitegravir Dosing in Patients with Hepatic Impairment:

- Stribild and Genvoya **should not be used** in patients with severe hepatic impairment.

Elvitegravir Dosing in Patients with Renal Impairment:

- Stribild **should not be initiated** in patients with estimated CrCl <70 mL/min, and it should be discontinued in patients with estimated CrCl <50 mL/min. FTC and TDF require dose adjustments in these patients, and these adjustments cannot be achieved with an FDC tablet.
- Genvoya **should not be initiated** in patients with estimated CrCl <30 mL/min.

Drug Interactions (see also the Adult and Adolescent Antiretroviral Guidelines and the HIV Drug Interaction Checker)

- *Absorption:* Elvitegravir (EVG) plasma concentrations are lower with concurrent administration of divalent cations because of the formation of complexes in the gastrointestinal tract and not because of changes in gastric pH. Because of this, Stribild and Genvoya should be administered at least 4 hours before or after administering antacids and supplements or multivitamins that contain iron, calcium, aluminum, and/or magnesium.[1]
- *Metabolism:* Stribild and Genvoya contain EVG and cobicistat (COBI). EVG is metabolized predominantly by cytochrome P450 (CYP) 3A4, secondarily by uridine diphosphate glucuronyl transferase 1A1/3, and by oxidative metabolism pathways. EVG is a moderate inducer of CYP2C9. COBI is a strong inhibitor of CYP3A4 and a weak inhibitor of CYP2D6; in addition, COBI inhibits the adenosine triphosphate-dependent transporters P-glycoprotein and the breast cancer resistance protein and the organic anion-transporting polypeptides OATP1B1 and OATP1B3. See the Cobicistat section for a more detailed summary of drug interactions. There is potential for multiple drug interactions when using both EVG and COBI. Neither Stribild nor Genvoya should be administered concurrently with products or regimens that contain ritonavir (RTV), due to the similar effects of COBI and RTV on CYP3A4 metabolism.
- *Renal elimination:* Drugs that decrease renal function or compete for active tubular secretion could reduce clearance of tenofovir disoproxil fumarate (TDF) or emtricitabine (FTC). Concomitant use of nephrotoxic drugs should be avoided when using Stribild. COBI inhibits MATE1, which increases serum creatinine levels up to 0.4 mg/dL from baseline in adults. Significant increases in serum creatinine levels may represent renal toxicity and should be evaluated.

Major Toxicities

- *More common:* Nausea, diarrhea, fatigue, headache, flatulence.
- *Less common (more severe):* Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported in patients receiving nucleoside reverse transcriptase inhibitors, including TDF and FTC. TDF caused bone toxicity (osteomalacia and reduced bone mineral density [BMD]) in animals when given in high doses. Decreases in BMD have been reported in both adults and children who were taking TDF; the clinical significance of these changes is not yet known. Evidence of renal toxicity has been observed in patients taking TDF, including a higher incidence of glycosuria, proteinuria, phosphaturia, and/or calciuria; increases in the levels of serum creatinine and blood urea nitrogen; and decreases in serum phosphate levels. Numerous case reports of renal tubular dysfunction have been reported in patients receiving TDF; patients at increased risk of renal dysfunction should be closely monitored if they are being treated with Stribild. Genvoya, which contains tenofovir alafenamide (TAF), has an improved bone and renal safety profile when compared to Stribild, which contains TDF. However, Genvoya is associated with greater increases in lipid levels than Stribild, according to findings from large-scale clinical trials.[2]

Resistance

The International Antiviral Society-USA (IAS-USA) maintains a list of updated resistance mutations and the Stanford University HIV Drug Resistance Database offers a discussion of each mutation. There is phenotypic cross-resistance between EVG and raltegravir.[3]

Pediatric Use

Approval

Stribild (EVG/c/FTC/TDF) is approved by the Food and Drug Administration (FDA) for use in children and adolescents aged ≥12 years and weighing ≥35 kg.[4,5] However, the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV recommends limiting the use of Stribild to adolescents

with sexual maturity ratings (SMRs) of 4 or 5 due to concerns about decreased BMD in pre-pubertal patients.

Genvoya (EVG/c/FTC/TAF) is approved by the FDA for use in children and adolescents weighing ≥25 kg with any SMR.[2]

Efficacy in Clinical Trials

EVG/c/FTC/TDF was found to be noninferior to a regimen of efavirenz/emtricitabine/TDF (EFV/FTC/TDF)[6] and noninferior to a regimen of atazanavir/ritonavir (ATV/r) plus FTC/TDF in adults at 144 weeks of treatment.[7] In two studies, 1,733 adults were randomly assigned to receive either EVG/c/FTC/TDF or EVG/c/FTC/TAF.[8] After 48 weeks, those receiving EVG/c/FTC/TAF had significantly smaller mean serum creatinine increases (0.08 vs. 0.12 mg/dL; $P < 0.0001$), significantly less proteinuria (median percent change in protein -3% vs. +20%; $P < 0.0001$), and a significantly smaller decrease in BMD at the spine (mean percent change -1.30% vs. -2.86%; $P < 0.0001$) and hip (-0.66% vs. -2.95%; $P < 0.0001$). Larger increases in fasting lipid levels were observed with EVG/c/FTC/TAF than with EVG/c/FTC/TDF; the median increases in levels of total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides were all higher in patients who received EVG/c/FTC/TAF.

Formulations

EVG is an integrase strand transfer inhibitor that is metabolized by CYP3A4. EVG must be used in the fixed-dose combination products Stribild[5] or Genvoya,[2] both of which contain COBI (see below). COBI itself does not have antiretroviral (ARV) activity, but it is a CYP3A4 inhibitor that acts as a pharmacokinetic (PK) enhancer, similar to RTV.[9]

Stribild is approved by the FDA as a complete ARV regimen for ARV-naive adults and adolescents with HIV aged ≥12 years and weighing ≥35 kg. It can also be used to replace the current ARV regimen in those who have been virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen for at least 6 months with no history of treatment failure and no known mutations associated with resistance to the individual components of Stribild.[5] Trials have shown that Stribild is noninferior to regimens that contain FTC plus TDF plus ATV[10,11] or FTC plus TDF plus EFV.[12,13] COBI inhibits renal tubular secretion of creatinine, and serum creatinine will often increase soon after initiating treatment with Stribild. Therefore, creatinine-based calculations of estimated glomerular filtration rate (GFR) will be altered, even though the actual GFR might be only minimally changed.[14] People who experience a confirmed increase in serum creatinine levels >0.4 mg/dL from baseline should be closely monitored for renal toxicity; clinicians should monitor creatinine levels for further increases and perform a urinalysis to look for evidence of proteinuria or glycosuria.[5] Careful periodic evaluation of renal function is warranted, because Stribild contains TDF, which has been associated with renal toxicity. This nephrotoxicity may be more pronounced in patients with pre-existing renal disease.[5]

Genvoya is approved by the FDA as a complete ARV regimen for ARV-naive children with HIV weighing ≥25 kg. It can also be used to replace the current ARV regimen in those who have been virologically suppressed (HIV RNA <50 copies/mL) on a stable ARV regimen for at least 6 months with no history of treatment failure and no known mutations associated with resistance to the individual components of Genvoya.[2] Because Genvoya contains TAF instead of TDF, Genvoya is expected to have a lower risk of bone and renal toxicity than Stribild. Two studies of adults have shown that fewer cases of renal and bone toxicity occurred among patients who received Genvoya than among those who received Stribild. After 48 weeks of treatment, participants who were treated with Genvoya had significantly smaller increases in levels of serum creatinine, less proteinuria, and smaller decreases in BMD at the spine and hip than participants treated with Stribild.[8] In children aged ≥6 years and weighing ≥25 kg who were treated with TAF-containing regimens, no clinically relevant changes were observed in BMD, levels of serum creatinine, and estimated GFR between baseline and 48 weeks of treatment.[15]

Coadministration of Elvitegravir, Cobicistat, and Darunavir

The combination of Stribild or Genvoya plus darunavir (DRV) may provide a low pill burden regimen

for ART-experienced individuals. However, an unfavorable drug interaction between EVG/c and DRV is possible, and the available data on the magnitude of the interaction are conflicting. There are also conflicting data on the efficacy of the combination in adults.[16-22]

The most rigorous drug interaction study, performed in HIV-seronegative adults, found 21% lower DRV trough concentrations and 52% lower EVG trough concentrations with DRV 800 mg plus EVG/c 150 mg/150 mg once daily compared to administration of either darunavir/cobicistat 800 mg/150 mg once daily or EVG/c 150 mg/150 mg once daily alone.[16] The actual trough values were 1,050 ng/mL for DRV and 243 ng/mL for EVG.

Despite the findings of the aforementioned drug interaction study in HIV-seronegative adults, the most rigorous efficacy evaluation found that among 89 treatment-experienced adults who were receiving five-tablet ARV regimens, 96.6% achieved virologic suppression (HIV RNA <50 copies/mL) 24 weeks after simplifying their regimens to a two-tablet regimen of Genvoya plus DRV 800 mg once daily.[20] Intensive PK sampling was performed in 15 of these patients (17%). Mean DRV and EVG troughs were 1,250 ng/mL and 464 ng/mL, respectively.

Given the uncertainly around the true magnitude of the drug interaction and the absence of data in children, this combination should be used with caution in children.

Use of Elvitegravir as Genvoya in Children Weighing <25 kg

Genvoya is not approved to treat children weighing <25 kg.[2,5] An ongoing study is evaluating the use of Genvoya in children aged <6 years and weighing <25 kg.

Use of Elvitegravir as Genvoya in Children Weighing ≥25 kg

Genvoya is approved by the FDA to treat children with any SMR who weigh ≥25 kg;[2] this approval was based on 24 weeks of data in 23 children.[23] In this study, children who had been virologically suppressed (HIV RNA <50 copies/mL) for at least 6 months were switched from their current regimens to Genvoya. There were no study discontinuations due to medication toxicity, but a concerning decline in CD4 T lymphocyte (CD4) cell counts was observed in these 23 children over the first 24 weeks of Genvoya treatment. CD4 counts declined by a median of 130 cells/mm^3 (with a range of -472 cells/mm^3 to 266 cells/mm^3) from baseline. However, after enrolling additional children (for a total of 52 participants), the median CD4 count decline at 48 weeks was 25 cells/mm^3.[24] The mechanism for the reduction in CD4 count is unclear, and this reduction has only been observed in this study. Plasma exposures of all four drugs were higher in these children than the plasma exposures seen in historical data from adults, but there was no association between plasma exposures of the four components of Genvoya and CD4 counts.[25]

Use of Elvitegravir as Stribild or Genvoya in Adolescents Aged 12 to 18 Years and Weighing ≥35 kg

Studies of the use of Stribild and Genvoya in children with HIV aged ≥12 years and weighing ≥35 kg have demonstrated safety and efficacy similar to that seen in adults through 24 weeks and 48 weeks of study, respectively; these formulations are approved by the FDA for use in this age/weight group.[5] Genvoya is preferred over Stribild when treating children with SMRs 1 to 3, as Genvoya carries a lower risk of renal and bone toxicity than Stribild.[2] Stribild is not approved to treat children weighing <35 kg.[5]

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